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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/077, 194     | 12/04/98    | BOHN                 | M 02481, 1596       |

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EXAMINER

KIM, V

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1614     | 14           |

DATE MAILED: 04/17/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**RECEIVED**

APR 18 2000

FINNEGAN, HENDERSON, FARABOW,  
GARRETT AND DUNNER, LLP

Docketed 4-18-00 Attorney CPE-APL-J25  
Case 02481-1596  
Due Date 7-17-00 URGENT  
Action RESPONSE DUE  
By [Signature]

APR 19 2000

(M)

## Office Action Summary

|                               |                            |
|-------------------------------|----------------------------|
| Application No.<br>09/077,194 | Applicant(s)<br>Bohn et al |
| Examiner<br>Vickie Kim        | Group Art Unit<br>1614     |

Responsive to communication(s) filed on \_\_\_\_\_.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

Claim(s) 27-30 and 32-37 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 27-30 and 32-37 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1614

## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on Feb. 09, 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/077,194 is acceptable and a CPA has been established. An action on the CPA follows.

### ***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 27-30 and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohaus et al (US 4,797,409) and Dittmar (US 4,185,106).

Claims read on a pharmaceutical composition comprising a component which contains 1-hydroxy-2-pyridone as a main moiety (note that this said components are generally called, 1-hydroxy-2-pyridones), and further comprising optionally at least one anionic, cationic, nonionic, or amphoteric surfactant, or a mixture thereof, and the preparation of the said composition.

Dittmar et al. (US'106) teach a shampoo containing 1-hydroxy-2-pyridones of the general formula which required by the instant claims: See abstract. The reference teaches that the patented composition could be incorporated with a great variety of cosmetic composition, especially with shampoos: see column 4, lines 49-52. The reference futher teaches additional pharmaceutic acceptable carriers such as surfactants (e.g. anionic, cationic, non-ionic and

Art Unit: 1614

amphoteric): See column 5, lines 1-68. Applicant's claim 37 are suggested in the cited patent; see column 2, lines 48 (e.g. 1-hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2(1h)pyridone).

Claims 29-30 which limit the concentration of pyridones, are also taught in column 7, lines 33-44.

Claims could be different from Dittmar's reference when R4 is substituted with a radical of formula II because there are certain species of R4 are not listed in the Dittmar et al's reference.(e.g. R4= a radical of formula II).

Lohaus et al. teach an anti-dandruff(antimycotic) composition comprising the claimed 1-hydroxy -6-substituted 2-pyridones which are required by the instant claims. For instance, claims 27-33 are suggested in the cited patent; see abstract and column 2 lines 54-55 (e.g.1-hydroxy-4-methyl-6-[4-(4-chlorophenoxy)phenoxy]methyl]-2pyridone).

It would have been obvious to one of ordinary skill in the art to substitute a radical of formula II for R4 position when Dittmar et al's teaching is taken in view of Lohaus because Lohaus et al teach the deficiency of Dittmar's reference.

One would have been motivated to do so because both teachings are drawn to 1-hydroxy-2-pyridones which share general chemical and physical properties and the new substituted formulations would be distinguished by increased their fungicidal activity and a retention time at the site of infection. The modified composition would increase benefits by adding stronger antibacterial and antiviral properties. Furthermore, one would have been motivated to make a shampoo that has a pH of 4.5-6.5 because hair shampoo containing acidic additives as well

Art Unit: 1614

known to the skilled artisan, can be formulated with the patented compound as cited in the Dittmar's reference; see column 9, lines 44-42.

***Response to Arguments***

4. Applicant's arguments filed on Jan, 21, 2000 have been fully considered but they are not persuasive.

It is noted that **a recitation of the intended use of the claimed invention must result in a structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. **If the prior art structure is capable of performing the intended use, then it meets the claim.** See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

In other words, the recitation "treatment for seborrheic dermatitis" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

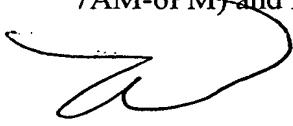
Art Unit: 1614

For the PH range required by the instant claims, the patented composition has same PH range because it is inherently possessed properties when the patented composition comprises exactly same ingredients, even though the cited patent didn't expressly suggest the claimed invention; see Dittmar's reference column 9, line 27.

Thus the claimed subject matter is not patentably distinct over the prior references.

***Conclusion***

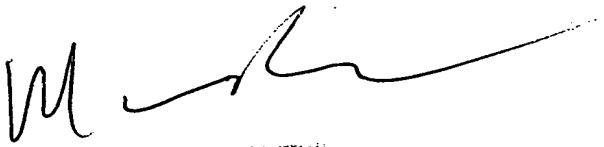
5. All the pending claims are rejected.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Vickie Kim* whose telephone number is (703) 305-1675 (Monday-Thursday: 7AM-6PM)-and Fax number is (703) 308-7924.



*Vickie Kim,*

Patent examiner

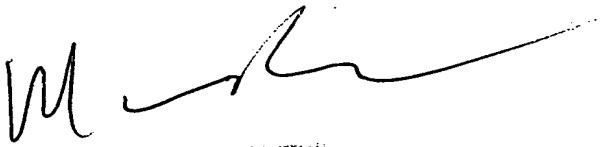
April 14, 2000



*William Jarvis*

Primary examiner

Art unit 1614



M. CINTAS  
ARTENEX EXAMINER  
GROUP 120